K123216

FEB 07 2013

510(k) Summary

In accordance with 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Information:

Submitter name:	**Aïmago SA** Parc Scientifique EPFL PSE-D, 4th floor 1015 Lausanne, Switzerland
Contact person during review:	Marc André
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Mailto:	Marc.Andre@aimago.com
Submission Number:	K123216
Date prepared (updated):	5 February 2013

Device Name:

Proprietary name:	Aïmago EasyLDI
Common name:	Laser Doppler Imager
Class	Class II
Classification name:	21 CFR 870.2120, Extravascular blood flow probe
Product code:	DPT
Review panel:	Cardiovascular
Proprietary name:	EasyLDI Studio
Common name:	Viewing software for use on a desktop computer (accessory)
Class	unclassified
Classification name:	Medical computer and software
Product code:	LNX
Review panel:	Cardiovascular

Predicate Device:

Substantial Equivalence is claimed with the predicate device:

- K121429 Aïmago EasyLDI (cleared 10 August 2012) manufactured by Aïmago S.A., Parc Scientifique EPFL, 1015 Lausanne (Switzerland)

The subject and predicate devices are prescription devices, and use Laser Doppler imaging technology to achieve an intended use of blood flow measurements in the microcirculation. The subject device in this 510(k) submission contains software applications for ease of use to the operator for microcirculation measurement in burn wounds, skin flaps and hand surgery. These

new software applications are intended only as an aid to healthcare professionals in their clinical assessments. The subject device of this 510(k) submission and its software do not provide specific clinical assessments such as burn depth assessments or potential healing times. In comparison to the predicate device K121429, the changes to the new subject device and its software applications do not adversely affect the safety and effectiveness of the device when used as labeled.

Device Description:

The **Aïmago EasyLDI** microcirculation camera is a device for imaging blood flow in the microcirculation. It is a medical diagnostic imaging device which serves to visualize the perfusion of cutaneous microcirculation in the form of arbitrary units in real-time. The EasyLDI uses the established laser Doppler technique performing a 2-dimensional area scan to build up a color coded image of the blood flow in the tissue. In the form of arbitrary units, this image allows the surgeon to quantify movement of blood cells beneath the skin surface.
The software changes implemented in the Aïmago EasyLDI microcirculation camera V2.X allow the user different modes of displaying the information on the built-in screen, thus facilitating the assessment of the microcirculation patterns for the specified applications.

EasyLDI Studio is a standalone software which runs on Windows systems. It is an optional accessory to the Aïmago EasyLDI microcirculation camera. It can be used to view LDI items (i.e. LDI snapshots, videos or references previously recorded with the Aïmago EasyLDI) on a commercially available desktop computer.

Intended Use:

The Aïmago EasyLDI Microcirculation Camera is intended for blood flow measurements in the microcirculation. In particular, it can be used for measuring perfusion of healthy and injured skin including burn wounds, skin flaps (plastic and reconstructive surgery) and hand surgery.

EasyLDI Studio is intended to be used as offline viewer application for snapshots, videos and references recorded with the Aïmago EasyLDI Microcirculation Camera.

Applications:

The Aïmago EasyLDI microcirculation camera is a medical diagnostic imaging device which serves to visualize and measure the perfusion of cutaneous microcirculation in the form of arbitrary units in real-time for applications such as:

- Visualizing & measuring the blood flow in healthy or injured skin
  - on burn wounds
  - in plastic and reconstructive surgery (skin flaps or hand surgery)
  - in clinical research

Comparison of Technological Characteristics:

Both the new and predicate devices use the established laser Doppler technique performing a 2-dimensional area scan to build up a color coded image of the blood flow in the tissue. In the form of arbitrary units, this image allows the surgeon to quantify movement of blood cells beneath the skin surface.

The software changes implemented in the Aïmago EasyLDI microcirculation camera V2.X allow the user different modes of displaying the information on the built-in screen, thus facilitating the assessment of the microcirculation patterns for the specified applications.

Summary of Testing:

Testing has been performed in-house as well as at contract laboratories has demonstrated that the Aïmago EasyLDI fulfills the requirements for Subpart B of Part 15 for Class A digital devices according to the FCC Rules for Digital Devices, the requirements ESD safety and electromagnetic immunity according to standard IEC 60601-1-2 and all electrical safety requirements from IEC 60601-1.

Conclusion:

Based upon comparison of the intended use, the applied technology, and the literature data provided, the Aïmago EasyLDI is substantially equivalent to the legally marketed predicate device K121429.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Aimago SA
% Mr. Marc Andre
Chief Technology Officer
Parc Scientifique EPFL D
4th Floor
Lausanne, Switzerland 1015

February 7, 2013

Re: K123216
Trade/Device Name: EasyLDI Microcirculation Camera
Regulation Number: 21 CFR 870.2120
Regulation Name: Extravascular blood flow probe
Regulatory Class: Class II
Product Code: DPT
Dated: January 18, 2013
Received: January 25, 2013

Dear Mr. Andre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123216

Device Name: EasyLDI Microcirculation Camera

Indications for Use:

The Aïmago EasyLDI Microcirculation Camera is intended for blood flow measurements in the microcirculation. In particular, it can be used for measuring perfusion of healthy and injured skin including burn wounds, skin flaps (plastic and reconstructive surgery) and hand surgery.

EasyLDI Studio is intended to be used as offline viewer application for snapshots, videos and references recorded with the Aïmago EasyLDI Microcirculation Camera.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2013.02.07 12:00:56 -05'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number ___K123216___